SINUS DECONGESTION- pseudoephedrine hcl tablet, film coated Kroger Company

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Kroger 44-112

Active ingredient (in each tablet)

Pseudoephedrine HCl 30 mg

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- temporarily relieves sinus congestion and pressure

Warnings

Do not use

if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease
- diabetes
- thyroid disease
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland

When using this product

do not exceed recommended dosage.

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or occur with fever

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years and over	take 2 tablets every 4 to 6 hours; do not take more than 8 tablets in 24 hours
children ages 6 to 11 years	take 1 tablet every 4 to 6 hours; do not take more than 4 tablets in 24 hours
children under 6 years	do not use

Other information

- each tablet contains: calcium 15 mg
- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, silicon dioxide, titanium dioxide, triacetin

Questions or comments?

1-800-632-6900

Principal Display Panel

Kroger®

COMPARE TO the active ingredient of Sudafed ${\bf @}$ Sinus Congestion *see bottom panel

NDC 30142-641-22

Maximum Strength

Pseudoephedrine Hydrochloride tablets

Nasal Decongestant

NON-DROWSY

Relieves:

Nasal & Sinus congestion Sinus Pressure

Actual Size

48 TABLETS 30 mg EACH

OUR PHARMACIST RECOMMENDED

DISTRIBUTED BY THE KROGER CO. CINCINNATI, OHIO 45202 FOR MORE PRODUCT INFORMATION,SCAN UPC USING YOUR KROGER APP OR CALL 800-632-6900

*Sudafed is a registered trademark of Johnson & Johnson Corporation, New Brunswick, NJ 08933. Johnson & Johnson Corporation is not affiliated with The Kroger Co. or this product.

Our Brands. Our Guarantee. Like it or your money back. www.kroger.com

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TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING





Kroger 44-112

SINUS DECONGESTION

pseudoephedrine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-641
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg

Inactive Ingredients	
Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics				
Color	red	Score	no score	
Shape	ROUND	Size	7mm	
Flavor		Imprint Code	44;112	
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:30142- 641-08	1 in 1 CARTON	04/13/2021			
1		24 in 1 BLISTER PACK; Type 0: Not a Combination Product				
2	NDC:30142- 641-22	2 in 1 CARTON	04/13/2021			
2		24 in 1 BLISTER PACK; Type 0: Not a Combination Product				

Marketing In	formation		
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC monograph final	part341	04/13/2021	

Labeler - Kroger Company (006999528)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(30142-641)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	pack(30142-641)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(30142-641)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(30142-641)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(30142-641)

Revised: 4/2021 Kroger Company